

DEC 18 2002

XIII. SUMMARY OF SAFETY AND EFFECTIVENESS



K024102

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DENTAL POWDER-FREE LATEX EXAMINATION GLOVES WITH PROTEIN LABELING CLAIM

Manufacturer: Allegiance Healthcare Corporation
1500 Waukegan road
McGaw Park, IL 60085

Regulatory Affairs Contact: Erica Sethi
Allegiance Healthcare Corporation
1500 Waukegan Road, Bldg. K
McGaw Park, IL 60085

Telephone: (847) 785-3337

Date Summary Prepared: 11/20/02

Product Trade Name: Undetermined

Common Name: Examination Glove

Classification: Patient Examination Glove

Predicate Devices: Dental Latex Powdered Examination Gloves

Description: Dental Powder-Free Latex Examination Gloves are formulated using natural rubber latex and offered non-sterile.

Intended Use: These examination gloves are disposable devices intended for medical purposes that are worn on the examiner's hands or fingers to prevent contamination between patient and examiner. These Dental Latex Examination Gloves are intended specifically for Dentistry and will be worn during dental cleaning, filling and examination in non-sterile environments within hospitals and other healthcare facilities.

Substantial Equivalence: The Dental Powder-Free Latex Examination Gloves With Protein Labeling Claim are substantially equivalent to Dental Latex Powdered Examination Gloves in that they provide the following characteristics:

- same intended use
- same sizes, configuration, packaging
- both made of natural rubber latex
- same tensile strength and thickness profiles
- both hand specific non-sterile examination gloves

Summary of Testing:

<u>Test</u>	<u>Result</u>
Primary Skin Irritation	Gloves do not display any potential for irritation.
Guinea Pig Maximization	Gloves do not display any potential for irritation.
Ultimate Elongation & Tensile Strength	Gloves meet or exceed requirements for rubber examination gloves per ASTM D3578-01.
Barrier Defects	Gloves meet or exceed requirements per 21 CFR §800.20 and ASTM D 3578-01.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 2002

Ms. Erica Sethi
Regulatory Affairs
Allegiance Healthcare Corporation
1500 Waukegan Road, Building K
McGraw Park, Illinois 60085

Re: K024102

Trade/Device Name: Dental Powder-Free Latex Examination Gloves with
Protein Labeling Claim

Regulation Number: 880.6250

Regulation Name: Patient Examination Gloves

Regulatory Class: I

Product Code: LYY

Dated: November 20, 2002

Received: December 12, 2002

Dear Ms. Sethi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



✓ Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



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Applicant: Allegiance Healthcare Corporation

510(k) Number:

Device Name: Dental Powder-Free Latex Examination Gloves With Protein Labeling Claim

Indications For Use: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

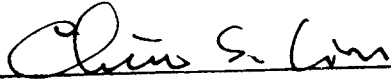
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

or

Over-The Counter Use _____


(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K 024102